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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,911	01/30/2004	Frederic Sgier	09955.0025-00000	4613
22852 7590 11/21/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413				
			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 11/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/766,911	Applicant(s) SGIER ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The amended drawings filed on September 26th, 2007 are acknowledged and accepted by the examiner. The corresponding drawing objections are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 recites the limitation "the aperture of the cap has a **spherical** cross-section ...". The aperture as disclosed in the specification as originally filed refers to element 17 which is defined as conical, not spherical. For examination purposes, it is assumed that applicant meant to define the lateral undercuts (**18**) of the cap as being spherical.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al (US 5,368,594) in view of Vignaud et al (US Patent 5,176,680) and in further view of Schlapfer et al (US Patent 5,501,684).

Martin et al disclose a vertebral arthrodesis device (**Figures 1-4**) comprising: at least two pins (**3**); screws (**5b**) having a head with a cavity (**11**) to receive a pin (**3**); the head having two lateral threaded holes receiving two threaded fastening screws (**14**); a cap (**12**) configured to contact and secure the rod with the cavity (**11**) due to inwardly inclined side walls (**12a**); the cap (**12**) has a conical shape (see **Figure 4** with the inwardly tapered top portion consistent with **element 17 of applicant's device** as shown in **Figures 2 and 3**); the cavity (**11**) snapping onto the pin (**5**, **See Column 1, Line 63 through Column 2, Line 13 and Column 3, Line 63 through Column 4, Line 6** discussing "clipping the rods into the cavities prior to applying caps **12**"); and the cavity is able to perpendicular flex (relative to the longitudinal axis of the arthrodesis device) because of two inward pointing slots (**13, Figure 2**).

Martin et al fail to disclose spherical lateral undercuts to allow pivoting, a ring placed along the pin, and a spherical cavity capable of securing the pin (spinal rod) with a ring about it. Vignaud et al teaches a similar device with a bone-anchoring portion (**1**),

a split ring (9) slidable along the length of the spinal rod (6), clamping means (7, 8, and 18), spherical cavity (as seen in **Figure 2**), and spherical (are rounded) lateral undercuts (**Figures 1 and 3**, the areas of parts 5 and 17). The ring and lateral undercuts allow for pivoting of the spinal rod as shown in **Figure 2**. It is explained (**Column 1, Lines 1-20**) that fixed systems only allow rods to be placed perpendicular to pedicle screws and thus make it difficult to re-establish physiological curves of the spine. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Martin et al with the split ring and lateral undercuts of Vignaud to allow for placement of a rod in an orientation other than perpendicular to the pedicle screw in order to facilitate the positioning of the spine.

Schlapfer et al teaches in **Figure 2** a sliding ring to allow pivoting of the screw in a bone fixation device longitudinal cuts none of which go through entirely, but initiate at alternating ends of the ring. This allows greater flexibility of the ring while maintaining integrity. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the split ring in the combination of Martin et al and Vignaud et al with the teaching of Schlapfer et al to allow greater flexibility of the spinal rod while maintaining integrity.

Response to Arguments

Applicant's arguments filed September 26th, 2007 have been fully considered but they are not persuasive.

Applicant contends that Martin et al and Vignaud et al fail to disclose and teach at least one ring received within the cavity with snap-on installation. The test for

obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Martin et al explicitly disclose why one would desire snap-on fixation and Vignaud et al explicitly teach why one would desire a ring about the spinal rod. Therefore, one having ordinary skill in the art at the time of invention would have been able to combine the teachings of both references to achieve a snap-on installation utilizing a ring by appropriately designing related components (i.e. reshaping the cavity to be spherical, sizing the cavity to still be a snap-on fit, and lateral undercuts to allow pivoting).

Applicant additionally contends that the references do not disclose or teach a head having a cavity with a spherical contour. As described above, to appropriately receive a spherical component, one would look at the teaching of Vignaud et al and Schlapfer et al to see that complementary spherical shapes were designed to receive a ball ring.

Applicant finally contends that including a spherical cavity would destroy the functionality of Martin et al and Vignaud et al. This is not found persuasive in the slightest. Again, applicant is arguing bodily incorporation. All that has been gleaned from the Vignaud et al reference in regard the Martin et al reference was the teaching for allowing pivoting of the spinal rod to assist in re-establishing physiologic curvature.

Conclusion

Due to the newly applied 35 U.S.C. 112, first paragraph rejection, **this Office Action is Non-Final.**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
November 18th, 2007



EDUARDO ROBERT
SUPERVISOR, PATENT EXAMINER